



DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DOD–2018–HA–0062]

RIN 0720–AB75

TRICARE Pharmacy Benefits Program Reforms

AGENCY: Office of the Secretary, Department of Defense (DoD).

ACTION: Interim final rule.

SUMMARY: This interim final rule implements Section 702 of the National Defense Authorization Act for Fiscal Year 2018 (NDAA FY18). The law makes significant changes to the TRICARE Pharmacy Benefits Program, specifically it: updates co-payment requirements; authorizes a new process for encouraging use of pharmaceutical agents that provide the best clinical effectiveness by excluding coverage for particular pharmaceutical agents that provide very little or no clinical effectiveness relative to similar agents and for giving preferential status to agents that provide enhanced clinical effectiveness; and authorizes special reimbursement methods, amounts, and procedures to encourage use of high-value products and discourage use of low-value products with respect to pharmaceutical agents provided as part of medical services from authorized providers.

DATES: This interim final rule is effective [insert date of publication in the Federal Register].

Comments must be received by [insert 60 days from the date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: David W. Bobb, RPh, JD, Chief, Pharmacy Operations, Defense Health Agency (DHA), telephone (703) 681-2890.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose of the Interim Final Rule

This interim final rule implements Section 702 of the National Defense Authorization Act for Fiscal Year 2018 (NDAA FY18), which does three things: (1) It updates cost-sharing requirements for outpatient pharmaceutical prescriptions filled by retail pharmacies and the TRICARE mail order pharmacy program. (2) It authorizes a new Uniform Formulary process for encouraging use of pharmaceutical agents in the TRICARE Pharmacy Benefits Program that provide the best clinical effectiveness by excluding coverage for particular pharmaceutical agents that provide very little or no clinical effectiveness relative to similar agents and giving preferential status to agents that provide enhanced clinical effectiveness. (3) It authorizes special reimbursement methods, amounts, and procedures to encourage use of high-value products and discourage use of low-value products with respect to pharmaceutical agents provided as part of medical services from authorized providers. This interim final rule implements each of these three statutory changes. This is being issued as an interim final rule in order to implement expeditiously the reforms authorized by Section 702, as specifically authorized by subsection (b)(3) of that section. Based on that clear Congressional authority and intent, the Department finds that obtaining public comment in advance of issuing this rule is impracticable, unnecessary, and contrary to the public interest. Delaying expeditious implementation by waiting for public comments to this interim rule not only delays the significant cost savings to the government that will be realized through implementation but also continues to allow coverage of pharmaceutical agents that do not provide the best clinical effectiveness for beneficiaries. In addition, subsection (b)(3) of Section 702 states that “in order to implement expeditiously the reforms

authorized...(A) the Secretary of Defense may prescribe an interim final rule, (B) not later than one year after prescribing the interim final rule and considering public comments with respect to such interim final rule, by prescribing a final rule.” Clearly Congressional intent is to implement the authorized reforms quickly. Nonetheless, DoD invites public comments on this rule and is committed to considering all comments and issuing a final rule as soon as practicable (but not later than one year after issuance of this interim final rule).

B. Legal Authority for the Regulatory Action

This interim final rule is under the primary authority of 10 U.S.C. 1074g, 1079 and 1086, and Section 702 of NDAA-18. Specifically, section 702(b)(3) of NDAA-18 authorizes DoD to “prescribe such changes to the regulations implementing the TRICARE program . . . by prescribing an interim final rule.” TRICARE program regulations (32 CFR Part 199) are issued under statutory authorities including 10 U.S.C. 1074g (the Pharmacy Benefits Program) and 10 U.S.C. 1079 and 1086 (TRICARE medical benefits). Section 702 of NDAA-18 amends both section 1074g and section 1079 (the section 1079 amendment being automatically applicable to section 1086).

C. Summary of Major Provisions of the Interim Final Rule

The major provisions of the interim final rule are the following.

1. Updating Cost-Sharing. Under the authority of section 1074g(a)(6), as amended by Section 702(a) of NDAA FY18, we are amending 32 CFR 199.21(i) to cross reference the statutory changes.

2. Uniform Formulary Changes. Based on section 1074g(a)(10), as added by Section 702(b)(1) of NDAA FY 18, we are changing the Uniform Formulary process under 32 CFR 199.21(e) by authorizing the exclusion of any pharmaceutical agent that provides very little or no

clinical effectiveness relative to similar agents, and preferential status for pharmaceutical agents that have enhanced clinical effectiveness relative to similar agents.

3. Pharmaceutical Agents as Part of Medical Services. Based on 10 U.S.C. 1079(q), as added by Section 702(b)(2) of NDAA FY18, we are changing provisions of 32 CFR 199.14 to authorize the adoption of special reimbursement methods, amounts and procedures to encourage the use of high value products and discourage the use of low value products – both relative to similar agents – in connection with pharmaceutical agents provided as part of outpatient medical services covered by TRICARE.

II. Provisions of Interim Final Rule

A. Updating Co-payments

The interim final rule amends 32 CFR 199.21(i)(2), which is the paragraph of the TRICARE regulation that governs cost-sharing amounts under the Pharmacy Benefits Program. The amended language simply cross references the statutory specifications on cost-sharing, including the table set forth in 10 U.S.C. 1074g(a)(6)(A). This table lists cost sharing amounts for the years 2018 through 2027 for generic, formulary, and non-formulary pharmaceutical agents dispensed by retail network pharmacies and the mail order pharmacy program. Two exceptions are that there is a \$0 cost-share for vaccines/immunizations authorized as preventive care for eligible beneficiaries and provided by retail network pharmacies and a \$0 cost-share for smoking cessation pharmaceutical agents covered under the smoking cessation program. Another special rule under the statute is that for survivors of members who die on active duty and for disability retirees and their families, cost-sharing increases will not apply, and the 2017 amounts will remain in effect. The interim final rule also provides that for any year after 2027, the cost-sharing amounts will reflect changes in the costs of pharmaceutical agents and

prescription dispensing, calculated separately for generic, formulary, and non-formulary drugs in each applicable point of service.

B. Uniform Formulary Changes

The interim final rule amends 32 CFR 199.21(e)(3) to provide that the Pharmacy and Therapeutics Committee may recommend and the Director may, after considering the comments and recommendations of the Beneficiary Advisory Panel, approve special uniform formulary actions to encourage use of pharmaceutical agents that provide the best clinical effectiveness to covered beneficiaries and DoD, including consideration of better care, healthier people, and smarter spending. Such special actions may operate as exceptions to the normal rules and procedures. Specifically, the Pharmacy and Therapeutics Committee may recommend complete or partial exclusion from the pharmacy benefits program of any pharmaceutical agent the Director determines provides very little or no clinical effectiveness relative to similar agents – i.e., other pharmaceutical agents in the same drug class – to covered beneficiaries and DoD. A partial exclusion under this paragraph may take the form (as one example) of a limitation on the clinical conditions, diagnoses, or indications for which the pharmaceutical agent may be prescribed. (As an example of this, off-label uses of a pharmaceutical agent may be disallowed.) A partial exclusion may be implemented through preauthorization or other means recommended by the Pharmacy and Therapeutics Committee. In the case of a partial exclusion, a pharmaceutical agent may be available on the non-formulary tier of the uniform formulary for limited purposes and for other purposes be excluded. In addition, the Pharmacy and Therapeutics Committee may recommend to the Director giving preferential status – based on a determination of enhanced clinical effectiveness relative to other agents in the same drug class – to any non-generic pharmaceutical agent of the uniform formulary by treating it for purposes of

cost-sharing as a generic product.

C. Pharmaceutical Agents as Part of Medical Services

The interim final rule amends 32 CFR 199.14(a)(6) and (j)(1) to provide that TRICARE may adopt special reimbursement methods, amounts, and procedures to encourage the use of high-value pharmaceutical agents as part of medical services furnished in a hospital outpatient setting or as part of any other medical services provided to TRICARE beneficiaries. Although TRICARE generally follows Medicare's reimbursement methodology when practicable for such medical services which include medically necessary administration of drugs, Section 702(b)(2) of NDAA FY18 authorizes the adoption of special reimbursement methods when determined appropriate to encourage the use of high-value pharmaceutical agents and discourage the use of low-value agents. For example, Medicare's reimbursement formula for physician-administered drugs paid under Part B is Average Sales Price (ASP) + 6%. Medicare and TRICARE reimburse providers ASP + 6 percent for the drug regardless of the price a provider pays for the drug.

Both Medicare and TRICARE acknowledge that such payment for physician-administered drugs does not incentivize high-value clinically driven, low cost drugs. To the contrary, the payment methods for physician-administered drugs using the ASP plus 6 percent raises many concerns including that it may encourage the use of more expensive drugs because the 6% add-on generates more revenue for more expensive drugs without regard to the relative clinical value of the product compared to other products in the same drug class. In order to remove the incentive for using higher priced products that have no higher clinical value, TRICARE may utilize the authority provided by the NDAA-18 to restructure – at least for certain selected drug classes, or categories of pharmaceuticals (identified in coordination with

the Pharmacy and Therapeutics Committee, or other entities as described in the implementing instructions) – the reimbursement amount. For example, TRICARE is evaluating established the ASP add-on as a percentage (likely 6 percent) of the median value of all drugs in a particular class, rather than attaching the 6% add-on to the ASP of a particular drug. The specific modifications to drug pricing for physician-administered drugs authorized by this IFR and NDAA FY18 shall be published in TRICARE’s implementing instructions (manuals) as approved by the Director, DHA, and shall be published on the health.mil website. The amendment to § 199.14(j)(1) will authorize this.

III. Regulatory Procedures

Interim Final Rule Justification

This is being issued as an interim final rule in order to implement expeditiously the reforms authorized by Section 702, as specifically authorized by subsection (b)(3) of that section. Based on that clear Congressional authority and intent, the Department finds that obtaining public comment in advance of issuing this rule is impracticable, unnecessary, and contrary to the public interest.

Executive Order (E.O.) 13771, “Reducing Regulation and Controlling Regulatory Costs”

E.O. 13771 seeks to control costs associated with the government imposition of private expenditures required to comply with Federal regulations and to reduce regulations that impose such costs. Consistent with the analysis of transfer payments under OMB Circular A–4, this interim final rule does not involve regulatory costs subject to E.O. 13771. Rather, this interim final rule affects only health care reimbursement payments under the TRICARE program. Aside from the “housekeeping” change to the regulation to incorporate the updated copayment

amounts enacted by Congress, the interim final rule makes two changes to the program: a new authority under the Uniform Formulary process and revised payment authority for pharmaceutical agents as part of medical services.

Executive Order 12866, “Regulatory Planning and Review” and Executive Order 13563, “Improving Regulation and Regulatory Review”

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This interim final rule has been designated a “significant regulatory action,” although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, this rule has been reviewed by the Office of Management and Budget (OMB).

The economic effect of these changes is limited to government reimbursements to health care providers/suppliers that under Circular A-4 are not considered as costs imposed on the economy. The expected reduction in government payments to pharmaceutical companies is based on some predicted increase in use of higher value medications and a corresponding decrease in the use of lower value medications in drug classes where different drugs have comparable clinical effect. The expected value of this shift in use of some medications – i.e., the quantity of the transfer payments – is \$30 million per year.

An initial analysis identified a sample group of candidate drugs that do not offer additional therapeutic benefit over other formulary items. By comparing the current costs to those of a lower-priced comparator and assuming similar utilization rates, the average cost

avoidance was \$1.5M/drug/year, with a more conservative cost avoidance of \$1M/drug/year. When fully implemented, this new process could average 30 drugs per year at a conservative cost avoidance of \$1M/drug/year.

Congressional Review Act, 5 U.S.C. 804(2)

Under the Congressional Review Act, a major rule may not take effect until at least 60 days after submission to Congress of a report regarding the rule. A major rule is one that would have an annual effect on the economy of \$100M or more or have certain other impacts.

This final rule is not a major rule under the Congressional Review Act.

Public Law 96-354, “Regulatory Flexibility Act” (RFA), (5 U.S.C. 601)

The Regulatory Flexibility Act requires that each Federal agency analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. This interim final rule is not an economically significant regulatory action, and it will not have a significant impact on a substantial number of small entities. Therefore, this rule is not subject to the requirements of the RFA.

Public Law 104-4, Sec. 202, “Unfunded Mandates Reform Act”

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of \$100M in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$140M. This interim final rule will not mandate any requirements for state, local, or tribal governments or the private sector.

Public Law 96-511, “Paperwork Reduction Act” (44 U.S.C. Chapter 35)

This rulemaking does not contain a “collection of information” requirement, and will not impose additional information collection requirements on the public under Public Law 96-511, “Paperwork Reduction Act” (44 U.S.C. chapter 35).

Executive Order 13132, “Federalism”

This interim final rule has been examined for its impact under E.O. 13132, and it does not contain policies that have federalism implications that would have substantial direct effects on the States, on the relationship between the national Government and the States, or on the distribution of powers and responsibilities among the various levels of Government. Therefore, consultation with State and local officials is not required.

List of Subjects in 32 CFR Part 199

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, Mental health, Mental health parity, Military personnel.

For the reasons stated in the preamble, the DoD amends 32 CFR part 199 as set forth below:

PART 199—CIVILIAN HEALTH AND MEDICAL PROGRAM OF THE UNIFORMED SERVICES (CHAMPUS)

1. The authority citation for part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

2. Section 199.14 is amended by revising paragraphs (a)(6)(i)(I) and (a)(6)(ii), and by adding paragraph (j)(1)(xi), to read as follows:

§ 199.14 Provider reimbursement methods.

* * * * *

(a) * * *

(6) * * *

(i) * * *

(I) Drugs administered other than by oral method. Drugs administered other than by oral method provided on an outpatient basis by hospitals are paid on the same basis as drugs administered other than by oral method covered by the allowable charge method under paragraph (j)(1) of this section.

* * * * *

(ii) Outpatient services subject to OPPS—(A) General. Outpatient services provided in hospitals subject to Medicare OPPS as specified in 42 CFR 413.65 and 42 CFR 419.20 will be paid in accordance with the provisions outlined in sections 1833t of the Social Security Act and its implementing Medicare regulation (42 CFR part 419) subject to exceptions as authorized by this paragraph (a)(6)(ii).

(B) Under the above governing provisions, TRICARE will recognize to the extent practicable, in accordance with 10 U.S.C. 1089(j)(2), Medicare's OPPS reimbursement methodology to include specific coding requirements, ambulatory payment classifications (APCs), nationally established APC amounts and associated adjustments (e.g., discounting across geographical regions and outlier calculations).

(C) While TRICARE intends to remain as true as possible to Medicare's basic OPPS methodology, there will be some deviations required to accommodate TRICARE's unique benefit structure and beneficiary population as authorized under the provisions of 10 U.S.C. 1079(j)(2).

(D) TRICARE is also authorized to deviate from Medicare's basic OPPS methodology to establish special reimbursement methods, amounts, and procedures to encourage use of high-

value products and discourage use of low-value products with respect to pharmaceutical agents provided as part of medical services from authorized providers. Therefore, drugs administered other than oral method provided on an outpatient basis by hospitals are paid on the same basis as drugs administered other than oral method covered by the allowable charge method under paragraph (j)(1) of this section.

(E) Temporary transitional payment adjustments (TTPAs). Temporary transitional payment adjustments will be in place for all hospitals, both network and non-network, in order to buffer the initial decline in payments upon implementation of TRICARE's OPPTS.

(1) For network hospitals. The temporary transitional payment adjustments will cover a four-year period. The four-year transition will set higher payment percentages for the ten Ambulatory Payment Classification (APC) codes 604-609 and 613-616, with reductions in each of the transition years. For non-network hospitals, the adjustments will cover a three year period, with reductions in each of the transition years. For network hospitals, under the TTPAs, the APC payment level for the five clinic visit APCs would be set at 175 percent of the Medicare APC level, while the five ER visit APCs would be increased by 200 percent in the first year of OPPTS implementation. In the second year, the APC payment levels would be set at 150 percent of the Medicare APC level for clinic visits and 175 percent for ER APCs. In the third year, the APC visit amounts would be set at 130 percent of the Medicare APC level for clinic visits and 150 percent for ER APCs. In the fourth year, the APC visit amounts would be set at 115 percent of the Medicare APC level for clinic visits and 130 percent for ER APCs. In the fifth year, the TRICARE and Medicare payment levels for the 10 APC visit codes would be identical.

(2) For non-network hospitals. Under the TTPAs, the APC payment level for the five clinic and ER visit APCs would be set at 140 percent of the Medicare APC level in the first year

of OPPTS implementation. In the second year, the APC payment levels would be set at 125 percent of the Medicare APC level for clinic and ER visits. In the third year, the APC visit amounts would be set at 110 percent of the Medicare APC level for clinic and ER visits. In the fourth year, the TRICARE and Medicare payment levels for the 10 APC visit codes would be identical.

(3) An additional temporary military contingency payment adjustment (TMCPA) will also be available at the discretion of the Director, Defense Health Agency (DHA), or a designee, at any time after implementation to adopt, modify and/or extend temporary adjustments to OPPTS payments for TRICARE network hospitals deemed essential for military readiness and deployment in time of contingency operations. Any TMCPAs to OPPTS payments shall be made only on the basis of a determination that it is impracticable to support military readiness or contingency operations by making OPPTS payments in accordance with the same reimbursement rules implemented by Medicare. The criteria for adopting, modifying, and/or extending deviations and/or adjustments to OPPTS payments shall be issued through TRICARE policies, instructions, procedures and guidelines as deemed appropriate by the Director, DHA, or a designee. TMCPAs may also be extended to non-network hospitals on a case-by-case basis for specific procedures where it is determined that the procedures cannot be obtained timely enough from a network hospital. For such case-by-case extensions, "Temporary" might be less than three years at the discretion of the DHA Director, or designee.

* * * * *

(j) * * *

(1) * * *

(xi) Pharmaceutical agents utilized as part of medically necessary medical services. In

general, the TRICARE-determined allowed amount shall be equal to an amount determined to be appropriate, to the extent practicable, in accordance with the same reimbursement rules as apply to payments for similar services under Medicare. Under the authority of 10 U.S.C. 1079(q), in the case of any pharmaceutical agent utilized as part of medically necessary medical services, the Director may adopt special reimbursement methods, amounts, and procedures to encourage the use of high-value products and discourage the use of low-value products, as determined by the Director. For this purpose, the Director may obtain recommendations from the Pharmaceutical and Therapeutics Committee under § 199.21 or other entities as the Director, DHA deems appropriate with respect to the relative value of products in a class of products subject to this paragraph. Among the special reimbursement methods the Director may choose to adopt under this paragraph is to reimburse the average sales price of a product plus a percentage of the median of the average sales prices of products in the product class or category. The Director shall issue guidance regarding the special reimbursement methods adopted and the appropriate reimbursement rates.

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3. Section 199.21 is amended by adding paragraph (e)(3), and by revising paragraphs (i)(2)(ii), (iv), and (x), to read as follows:

§ 199.21 TRICARE Pharmacy Benefits Program.

* * * * *

(e) * * *

(3) Special rules for best clinical effectiveness. (i) Under the authority of 10 U.S.C. 1074g(a)(10), the Pharmacy and Therapeutics Committee may recommend and the Director may, after considering the comments and recommendations of the Beneficiary Advisory Panel,

approve special uniform formulary actions to encourage use of pharmaceutical agents that provide the best clinical effectiveness to covered beneficiaries and DoD, including consideration of better care, healthier people, and smarter spending. Such special actions may operate as exceptions to the normal rules and procedures under 10 U.S.C. 1074g(a)(2), (5) and (6) and the related provisions of this section.

(ii) Actions under paragraph (e)(3)(i) of this section may include a complete or partial exclusion from the pharmacy benefits program of any pharmaceutical agent the Director determines provides very little or no clinical effectiveness relative to similar agents to covered beneficiaries and DoD. A partial exclusion under this paragraph may take the form (as one example) of a limitation on the clinical conditions, diagnoses, or indications for which the pharmaceutical agent may be prescribed. A partial exclusion may be implemented through any means recommended by the Pharmacy and Therapeutics Committee, including but not limited to preauthorization under paragraph (k) of this section. In the case of a partial exclusion, a pharmaceutical agent may be available on the non-formulary tier of the uniform formulary for limited purposes and for other purposes be excluded.

(iii) Actions under paragraph (e)(3)(i) of this section may also include giving preferential status to any non-generic pharmaceutical agent of the uniform formulary by treating it for purposes of cost-sharing as a generic product.

* * * * *

(i) * * *

(2) * * *

(ii) For pharmaceutical agents obtained from a retail network pharmacy, the cost share will

be as provided in 10 U.S.C. 1074g(a)(6), except that there is a \$0 cost-share for vaccines/immunizations authorized as preventive care for eligible beneficiaries.

* * * * *

(iv) For pharmaceutical agents obtained under the TRICARE mail order program, the cost share will be as provided in 10 U.S.C. 1074g(a)(6), except that there is a \$0 cost-share for smoking cessation pharmaceutical agents covered under the smoking cessation program.

* * * * *

(x) For any year after 2027, the cost-sharing amounts under this paragraph shall be equal to the cost-sharing amounts for the previous year adjusted by an amount, if any, determined by the Director to reflect changes in the costs of pharmaceutical agents and prescription dispensing, rounded to the nearest dollar. These cost changes, if any, will consider costs under the TRICARE pharmacy benefits program calculated separately for each of the following categories based on prescriptions filled in the most recent period for which TRICARE cost data are available, updated to the current year, if necessary, by appropriate industry data:

- (A) Generic drugs in the retail point of service;
- (B) Formulary drugs in the retail point of service;
- (C) Generic drugs in the mail order point of service;
- (D) Formulary drugs in the mail order point of service;
- (E) Non-formulary drugs.

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Dated: December 3, 2018.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer,

Department of Defense.

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